UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/290,029	04/09/99	BOTTOMLY H	

HM12/1206

BRENDA HERSCHBACH JARRELL
CHOATE HALL & STEWART
EXCHANGE PLACE
53 STATE
BOSTON MA 02109-2891

EXAMINER	
EWOLDT,G	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 12/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/290,029	Applicant(s) Bottomly et al.
	Examiner Gerald Ewoldt	Group Art Unit 1644

☒ Responsive to communication(s) filed on *Sep 26, 2000*.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☐ Claim(s) *1-281* is/are pending in the application.

Of the above, claim(s) *1-108, 110, 113-114, 117-121, 124, 127-128,* is/are withdrawn from consideration.

☐ ~~Claim(s)~~ *130-135, 140-141, 150-152, 157-159, 176-183, 186-187, 192-281* ~~is/are allowed~~.

☐ Claim(s) *109, 111-112, 115-116, 122-123, 125-126, 129, 136-139, 142-150,* is/are rejected.

☐ ~~Claim(s)~~ *153-156, 160-175, 184-185, and 188-191* ~~is/are objected to~~.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *9*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Claims 1-281 are pending.
Applicant's Response and Amendment, received 9/26/00, is acknowledged.

2. Newly amended claims 50-55, 60, 63-66, 79-81, 84-91, 94-97, 102-104, and 108 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:
the elected invention comprises a method of modulating an immune system response to an antigen away from a Th2 response comprising isolating one or more pAPC from an individual and exposing said pAPC to an inducing agent factor concurrently with exposure to a protein antigen then administering said pAPC to a subject, said elected species consisting of:
a) pAPC - dendritic cell,
b) factor - CpG (Th1 inducing agent),
c) antigen - crude antigen preparation,
d) targeting agent - Fc receptor ligand,
e) encapsulating device - liposome.

Claim 50 has been amended to recite a method of modulating presentation of an antigen. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 50-55, 60, 63-66, 79-81, 84-91, 94-97, 102-104, and 108 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Claims 61, 67-69, 82-83, 92-93, 98, 105-107, 110, 117, 127, 140-141, 151-152, 157, 176, 186-187, and 192-193 (non-elected species from Group XIV); 1-49, 56-59, 62, 70-78, 99-101, 113-114, 118-121, 124, 128, 130-135, 158-159, 177-183, and 194-281 (non-elected Inventions); as well as 50-55, 60, 63-66, 79-81, 84-91, 94-97, 102-104, and 108 (newly amended), are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

4. Claims 109, 111-112, 115-116, 122-123, 125-126, 129, 136-139, 142-150, 153-156, 160-175, 184-185, and 188-191 are pending and being acted upon.

5. In view of Applicant's amendment and response, filed 9/25/00, only the following rejections remains.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 109, 111-112, 115-116, 122-23, 125-126, 129, 136-139, 142-150, 153-156, 160-175, 184-185, and 188-191 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, Claims 109, 111-112, 115-116, 122-126, 129, 136-139, 142-150, 153-156, 160-175, 184-185, and 188-191 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is: administering isolated and exposed pAPC to a subject so as to modulate an immune response.

Applicant's arguments, filed 9/26/00, have been fully considered but they are not persuasive. Applicant argues that an amendment to Claim 1 has overcome the rejection and regerdless, modulating the response of T cells would comprise the modulation of an immune system without administration to said cells to a subject.

Regarding the alleged amendment of Claim 1, no amendment to Claim 1 has been received by the Office. Regardless, an amendment to Claim 1 would have no effect on the patentability of independent Claims such as Claim 109 or 160.

Regarding the assertion that modulating the response of T cells would comprise the modulation of an immune system without administration to said cells to a subject, Applicant's argument constitutes that argument that T cells alone, including T cells *in vitro*, would comprise "an immune system". Such a definition of "an immune system" would not be routinely recognized in the immunological arts (see Janeway et al., page 1, line 1).

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 109, 111-112, 115-116, 122-126, 129, 147, 156, 160-167, 175, and 191 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,994,126 in view of WO98/37919 and Romagnani (all of record), for the reasons set forth in Paper No. 7, mailed 6/21/00.

Applicant's arguments, filed 9/25/00, have been fully considered but they are not persuasive. Applicant argues against the references individually and argues a lack of motivation to combine the references. In response to Applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the use of a well known adjuvant/immunomodulator (CpG) to direct an immune response in a particular well known direction (towards Th1), said response including the direction/modulation of a well known cell type (dendritic cells), is not unobvious, for the reasons set forth in the previous Office action. Neither is the expectation of success unreasonable.

Applicant further argues that the scope of Claim 50 includes modulation of an immune response in directions other than away from Th2, however, due to Applicant's amendment, filed 9/25/00, Claim 50 is no longer under examination.

10. Claims 136-139, 142-144, 168-169, 184-185, and 188-190 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,994,126 in view of WO98/37919 and Romagnani (1997), as applied to claims 109, 111-112, 115-116, 122-126, 129, 147, 156, 160-167, 175, and 191 above, and further in view of Maurer et al. (of record), for the reasons set forth in Paper No. 7, mailed 6/21/00.

Applicant's arguments, filed 9/25/00, have been fully considered but they are not persuasive. Applicant argues that without the motivation to combine U.S. Patent No. 5,994,126 in view of WO98/37919 and Romagnani et al. the rejection should be withdrawn. See the Examiner's response in paragraph 8, supra.

11. Claims 87-89, 145-146, 148, and 170-173 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,994,126 in view of WO98/37919, Romagnani, as applied to claims

109, 111-112, 115-116, 122-126, 129, 147, 156, 160-167, 175 and 191 above, and further in view of WO98/33520 (of record), for the reasons set forth in Paper No.7, mailed 6/21/00.

Applicant's arguments, filed 9/25/00, have been fully considered but they are not persuasive. Applicant continues to argue that without the motivation to combine U.S. Patent No. 5,994,126 in view of WO98/37919 and Romagnani, and with no expectation of success, the rejection should be withdrawn. See the Examiner's response in paragraph 8, supra.

12. Claims 149-150, 153-155, 174, 184-185, and 188-190 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,994,126 in view of WO98/37919, Romagnani, and WO98/33520, as applied to claims 109, 111-112, 115-116, 122-126, 129, 145-148, 156, 160-167, 170-173, 175, and 191 above, and further in view of Maurer et al. (Of record), for the reasons set forth in Paper No. 7, mailed 6/21/00.

Applicant's arguments, filed 9/25/00, have been fully considered but they are not persuasive. Applicant argues that without the motivation to combine U.S. Patent No. 5,994,126 in view of WO98/37919 and Romagnani the rejection should be withdrawn. See the Examiner's response in paragraph 8, supra.

13. No claim is allowed.

14. The Zhang et al. reference in the supplemental IDS (paper No. 9) has not been considered because it is in Chinese.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
December 4, 2000

Christina Chan
CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP 1800 1600